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Appl. No.: 10/565,690

Amdt. Dated July 16, 2007

Response to Final Office Action Mailed April 23, 2007

**REMARKS:**

In the second, final Office Action, mailed April 23, 2007, the Examiner has withdrawn all prior rejections but now objects to the form of specific phrases or elements in claims 1, 2, 6, 7, 9, and 16-18 and so has rejected all the claims under 35 USC §112. Claims 1-6 and 9-15 are now or again rejected as anticipated by the previously cited Sanders '399 patent; claims 7 and 16-18 are again rejected as obvious on Sanders in view of the previously cited Kane application publication '492; and claims 8 and 19-20 are again rejected as obvious on Sanders in view of previously-cited Cooley '925 patent.

By a proposed Response filed by telefax on June 20, 2007, claims 1-20 currently pending were proposed to be amended to improve their forms, including removing all of the reference numerals, without any substantial narrowing of their subject matter except as to now meeting international and federal requirements for shipping of hazardous substances and products, such as IATA and US DOT regulations - a preamble recitation giving life and meaning to the claims. The claims were again distinguished from the cited prior art, which was argued to be directed to different problems than the present invention and so to have different structures that do not anticipate or make obvious the even more-clearly-claimed matter of the present invention.

In the July 2, 2007 Advisory Action Before the Filing of an Appeal Brief, the Examiner has refused to enter the Amendment After Final of June 20, finding that further consideration is required to determine if the amendments avoid the prior art and stating that a new search would

be necessary in view of the amendments. He has agreed that all section 112 objections are overcome by the proposed amendments of June 20, which are re-presented herewith.

In a telephone conference of July 9, 2007, between the Examiner and counsel, the proposed amendments to Claim 1 were discussed and agreed to distinguish the present invention from the Fig. 10-11 disclosure of Sanders, the principal reference, and to make Claim 1 allowable, subject to a further search of the art upon filing of this RCE.

The present invention is directed to a single-use, flexible shipping container with a secure, double seal, for containing hazardous biologic and other materials, the container meeting official requirements, such as IATA and US DOT regulations, for shipping the container and hazardous materials therein by commercial air transport. The package of this disclosure and claims is a single use package, to be filled, sealed, shipped, opened and emptied in a controlled environment, and then discarded and sent to be processed for safe disposal - not re-closed and re-sealed for further use as are the envelopes of the cited art.

The principal reference applied, Sanders '399, is directed not to an approved, single-use shipping container for air transport but to a reusable, re-sealable pouch having only a single seal over and about its slit 17. The Kane reference similarly shows not an approved air transport shipping container but a reusable, re-sealable consumer food package adapted for forming, filling, and sealing at high speeds in production lines, with no comments about security of the contents during shipping in reduced pressure environments. Cooley '925 discloses an authenticating and tamper-evident label involving microporous layers that are opaque when assembled but turn transparent upon tampering, but not for securely containing hazardous materials during air transport. None of the references, singly or together, make the claimed invention non-novel or obvious.

According to the present disclosure, a single-use package is provided having a slot 18 for insertion of a hazardous item such as a vial of biologic fluid, a tissue specimen, or the like, loss or spillage of which would be dangerous to an aircraft and its crew and to baggage or freight

handlers. A portion 20 of a double-sided adhesive strip 10 is pre-affixed on one of its sides 12, near one of its ends, to the outer wall 2, 9 of the package adjacent the slot 18, with protective film 15 covering the balance 14 of that side of the strip (Fig. 2). After the product is inserted, the protective film 15 is removed from the wall-side portion of the strip 10 and that one side 14 is pressed onto the outer wall 9, 23 of the package and across the slot 18, sealing the product into the package. Then the protective film 17 on the other side of the strip 10 is removed and the top 4 of the package is folded over at the slot 5, so that the adhesive strip 10 is bent back onto itself with the end 13 of the strip also adhering to the wall 2, 9 of the package below the other end 20 of the adhesive strip. This forms the double seal that is used to implement packaging in a novel, unobvious, and most useful way to comply as required with the international and federal specifications; indeed the packaging according to this disclosure has now successfully passed the IATA and US DOT certification tests.

**Rejections of Claims 1-6 and 9-15 on Sanders '399 patent, under 35 USC §102(b)**

The Sanders '399 patent is not directed to providing a single-use or safe, leakproof container for secure transport of hazardous materials, as is now required by all the claims. Sanders' arrangement does not form a double seal over the entirety of the opening of the slit 17 through the outer wall, for instance. Sanders provides a re-useable tape seal with a finger tab at 23 for reopening the adhesive joint, in contrast to the permanent, double seal of the present invention. See the Sanders disclosure, at col. 4 lines 1-46 (quoted in Applicant's response to the first office action). The Sanders package is only "substantially" airtight, and it is "easily openable" as by internal pressure -- these properties are simply not appropriate for hazardous material transport. No suggestion or teaching appears in Sanders that the upper surface of the sealing tape 21 in Figs. 1-2 has adhesive thereon, as is required in the present disclosure.

Figures 12-13 of Sanders do show a double-sided tape 50, with silicone release paper 52 on the upper side thereof in Fig. 12 (see col. 7, ll. 4-42). The tape 50 then adheres to itself across the slit 17 as is required in the present invention, but this comprises only a single seal across the

slit 17 as in Figure 12 of Sanders, not the double seal (at 12, 22 of application Fig. 4) required by the present invention to meet international and federal air shipping regulations. This disclosure in Sanders is properly not relied on by the Examiner in his consideration of the claims of the present application.

The Examiner's citation of Sanders' "substrate" 21, in Fig. 1, as a "detachable protective strip" (para. 9 of the action) that corresponds to the protective strip 17 of the present invention, Fig. 1, is incorrect. Substrate 21 of Sanders is disclosed as "adhesive tape", not release paper. As stated in the Sanders disclosure cited above, the adhesive 19 of Sanders is part of adhesive tape 21, being on the under-surface 22 of the substrate 21; adhesive 19 however adheres more strongly to the surface 18 of the package than to the surface 22 of the substrate 21. Therefore, as the substrate 21 is peeled upwardly to open the slit 17, the rightward portion of the adhesive in Fig. 2 of Sanders remains attached to the wall 18, while the leftward portion remains attached to both the substrate 21 and the wall 18, leftward of the slit 17. There is no adhesive on top of the substrate 21, so folding the package 10 and the substrate 21 back on themselves at the slit 17, as is done in Fig. 4 of the present disclosure (at slot 5) - even if done, contrary to all suggestions in Sanders - would not and cannot result in a double seal as is required by the present claims and by international and federal regulations for air transport of hazardous materials.

Sanders thus also has no protective release strip, as 15 of the present disclosure, on a lower surface of his adhesive 19, to keep his slit 17 open for insertion of product. Thus, there is nothing in Sanders corresponding to the larger protective strip 17 of Fig. 1 and claim 1 of the present application, nor is there anything corresponding to a detachable protective strip below adhesive 19 rightwardly of the slit 17 in Sanders as is claimed in the present case. Further, there is nothing in Sanders corresponding to the adhesive surfaces of the strip as defined in claim 1 of this application. Claim 1 is novel over Sanders.

We believe the Examiner indeed is incorrect that Sanders's tape 20 overlaps itself in Fig. 10. Fig 10 does seem at first glance to indicate that the left end of the right-hand portion of the

tape 20 extends inside the web or seal 46, by showing dashed lines across web 46, aligned with the upper and lower edges of the rightward portion of the tape 20 covering the slit 45. Fig. 11 is, according to Sanders (col. 3- lines 6-7), an elevation of the embodiment of the container shown in Fig 10, as, a view from the top of Fig. 10. On Fig 11, it is clear that the leftward end of the right-hand portion of the tape 20 does *not* extend to the inside of the web or seal 46, as indicated by Fig. 10. Therefore, there is a contradiction between the two figures; Fig. 11 should be interpreted as the correct view, because after separating the tape from one of the adjacent surfaces across the slot 45, the end portion of the wrapper is supposed to be allowed to disconnect from the remaining portion of the wrapper (Sanders col. 7, lines 23-30). This could not be achieved if the leftward end of tape 20 were inserted into and captured by the web seal 46.

Another way of considering the Sanders disclosure, differently from the above but perhaps more direct, is as follows. On Fig 10, the tape 20 does not overlap on itself the same way as tape 13, 20 does in the present disclosure, as in Fig. 4. Indeed, folding Sanders's sheet 44 on itself (Col. 7, lines 11-16) will not bring the adhesive coatings of two portions of the tape 20 in contact with each other because sheet 44 and protective layer 21 on tape 20 are still interposed.

Thus the only possible conclusion is that the dotted lines indicating the presence of the tape 20 beneath or inside the web or seal 46 on Fig 10 of Sanders are incorrect and should be disregarded, as it would be by one of ordinary skill in the art reviewing carefully the Sanders disclosure.

This gap in the sealing of tape 20 to the rectangular sheet 44 is why Sanders can claim only "substantial" air-tightness for his package. This would not be acceptable for an air transport container for hazardous materials.

The double sealing of the present disclosure and claims is necessary to sustain the seal as against the relative internal pressures to be encountered in air transport; "easy" opening and spillage from the Sanders package in the intended use, as shown in his "substantially airtight" admission in the specification, is wholly unacceptable. The structures and functions of the un-

filled bag as per claim 1 here and of the filled bag of method claim 9 are simply not provided by Sanders and are patentably novel over Sanders.

Independent claim 1 is allowable over Sanders since these several fundamental elements are not shown in nor suggested by Sanders, alone or in combination with the other art cited, nor within the ordinary skill of the art to add to or engraft onto Sanders' disclosure. Providing these elements in this combination is simply not within the province of one of ordinary skill in the art to devise and implement, but requires invention. The remaining claims 2-20 are allowable as all depend from and incorporate the novel and unobvious subject matter of claim 1.

The Examiner's rejection of claim 9 of the application as also anticipated by Sanders, based on the same analysis as is shown above to be faulty in regard to claim 1, is equally unavailing to show anticipation of claim 9. No single embodiment of Sanders has a "first protective strip covering [a] second zone of the adhesive strip", as is shown above, and Sanders discloses no second protective strip that may be removed from the first or outer face of the adhesive substrate, as the Examiner asserts. The Examiner's citation to multiple figures and disparate portions of the disclosure of Sanders, as Figs. 1, 3, and 10-11, and Col. 4, ll. 15-26 and 39-60, Col 5, ll. 11-15, and Col. 7, ll. 4-22 of Sanders, is inapposite to this rejection, as different structures of Sanders cannot be combined in a single embodiment; thus, this argument of the Examiner is not understood. Picking out unrelated bits and pieces of a reference to try to show anticipation is improper.

The rejections of independent claim 1 and method claim 9 of the application as anticipated by Sanders '399 patent are unwarranted. These rejections should be reconsidered and withdrawn, together with the similar rejections of claims 2-6 and 10-15 dependent from them.

**Rejections of Claims 7 and 16-18 on Sanders '399 in view of Kane appl'n, sec. 103**

Claims 7 and 16-18 of the present application claim oriented polyamide in an outer layer and polyethylene in an inner layer of the wall of the package of application claim 1. Since claim

1 is allowable, as demonstrated above, these claims are also allowable as incorporating the novel structure defined there.

These claims also are independently patentably non-obvious over the combination of art applied in paragraph 10 of the second, final action. Although Kane does disclose each of oriented polyamide in an outer layer of an envelope and various specific polyethylenes in an inner layer, such a "menu" disclosure, even in related-art patents, is frowned upon. *Medtronic Navigation v. Brainlab*, Fed. Cir. (06-1289) (non-precedential), Kane and Sanders together do not teach or suggest use of such materials in the structure defined in these claims of the present application, for providing a secure, internationally- and federally-approvable secondary packaging that is leakproof under air transport conditions, as is required by these claims. Such combination is not within the ordinary skill of the art.

**Rejections of Claims 8 and 19-20 on Sanders '399 in view of Cooley '925**

Claims 8 and 19-20 recite that the adhesive strip used to double-seal the envelope comprises at least one sheet of synthetic olefin polymer covered on two sides with a rubber-based adhesive. Since claim 1 is allowable, as demonstrated above, these claims are also allowable as incorporating the novel structure defined there.

These claims also are independently patentably non-obvious over the combination of art applied in paragraph 4 of the action. Although Cooley does disclose each of synthetic olefin polymer and rubber-based adhesive in the text cited, such "menu" disclosure in unrelated art (Cooley discloses tamper-evident seals, not recloseable seals as does Sanders) is frowned upon. *Medtronic Navigation v. Brainlab*, Fed. Cir. (06-1289) (non-precedential), Cooley and Sanders together do not suggest use of such materials in the structure defined in these claims of the present application, for providing a secure, internationally- and federally-approvable secondary packaging that is leakproof under air transport conditions, as required.

**"Answers to Applicant's Arguments" Rebutted**

The Examiner in paragraphs 12-17 of the April 23 action seeks to explain why the case was not allowable after the first amendment. Each of these explanations is now overcome or inapposite in view of the amendments made and explanations above.

As to paras. 12, 13, 15, and 17 of the Final office action, meeting the international and federal specification requirements - including for instance the IATA and US-DOT requirements, and providing a double seal over the entire length of the slot - are now expressly recited in Claim 1 and thus are incorporated into all the claims. The structure of Fig. 4 of the present application is very different from that of Fig. 13 of Sanders, for instance, even if the openability and re-sealability of the Sanders disclosure is discounted.

As to para. 14, applicants have made clear, in the text of Claim 1 as previously and now again presented and in their arguments above, the roles of the first and the second protective strips. Applicants claim not an "overlap" of adhesive over itself for a small portion of the slot for sealing same but that the double seal extends the full length of the slot. Indeed, a double seal that exists for only a portion of a slot is not an effective double seal and would not meet IATA or US-DOT specifications.

As to para. 16, Cooley discloses a tamper indicating label, not a secure package that is resistant to leakage under IATA and US-DOT test conditions. One of ordinary skill in the art would not look to Cooley to solve leakage problems left by the Sanders disclosure. Applicants have no issue with combining related art as Kane and Sanders, but Cooley is unrelated as he does not presume to provide "secure" packaging but only to indicate that a package has at least once been opened. Even if Cooley were to be combined with Sanders, however, there is no suggestion or motivation to make the present invention in any respect.



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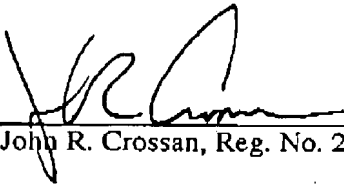
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**CONCLUSION**

The art cited does not anticipate or render obvious the combinations of elements and functions recited in any of claims 1-20 of the present application. Sanders '399 lacks the elongated "double-sticky" tape and protective covers arranged with the package or envelope as in the present disclosure and claims, and the other art cited does not make up for that shortfall. Each and all of claims 1-20 should be reconsidered and now allowed for issuance. Favorable reconsideration is earnestly requested. If any matters may be resolved in a further telephone conference, the Examiner is requested to telephone undersigned counsel for applicant.

*Deposit Account Charge Authorization and Extension Request.* The Commissioner is hereby authorized to charge the \$395.00 fee and any other fees associated with this RCE to our Deposit Account No. 50-0305, including any fees for any required extension of time under 37 CFR §1.136, which is hereby requested if necessary.

Respectfully submitted,

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I hereby certify that the attached correspondence, namely: Request for Continued Examination with Amendment and Reply, is being timely transmitted by facsimile on the date listed above, to the U.S. Patent Office at the facsimile number listed above, under 37 C.F.R. § 1.8.

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